

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hans Josef Stauss and Liqun Gao

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Serial No.: 09/625,963 Art Unit: 1644

Filed: July 26, 2000 Examiner: Francois Vandervegt

For: *IMMUNOTHERAPEUTIC METHODS USING EPITOPES OF WT-1 AND GATA-1*Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## DECLARATION UNDER 37 C.F.R. § 1.131

We, Hans Josef Stauss and Liqun Gao, hereby declare that:

1. We are co-inventors of the claimed subject matter.
2. We are familiar with the office action mailed November 3, 2004 in which claims 1, 5, 7, 15, and 19 were finally rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent Application Publication 20030082196 by Gaiger, et al., published on May 1, 2003, which claims priority to U.S. Serial no. 09/164,223 filed September 30, 1998. We are familiar with the U.S. Patent Application Publication 20030082196 by Gaiger, et al. that discloses peptides containing the amino acid sequence RMFPNAPYL (SEQ ID NO: 2 (human), SEQ ID NO: 185 (human), SEQ ID NO. 3 (mouse) and SEQ ID NO:293 (mouse)) at least at page 1 paragraph 0008 and at page 6 paragraph 0053.

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3. We conceived and reduced to practice the peptide containing the amino acid sequence RMFPNAPYL as defined by claims 1, 5, 7, 15, and 19 as currently pending in the above-identified patent application, prior to September 30, 1998 as demonstrated by the attached copies of pages from our laboratory notebooks (Exhibit B). This work was performed in our laboratory in London, United Kingdom.

4. The amino acid sequence of human WT-1 was manually scanned to identify candidate peptides (listed in Exhibit A) that had predicted HLA-A2 anchor residues. These candidate peptides were chemically synthesized and used for binding and cytotoxic T-cell (CTL) induction assays.

5. The peptide containing the amino acid sequence RMFPNAPYL, represented as buWT 126-34 in Exhibit A and as WT-1/126 in Exhibit B, bound to HLA-A0201, represented as HLA-A2 in Exhibit B, on T2 cells (Exhibit B, page 3). This demonstrates that we were in possession of peptides containing the amino acid sequence RMFPNAPYL and that the peptide binds to HLA-A0201-positive antigen presenting cells (APC). As noted in Exhibit B, pages 7-8, cytotoxic T-cells (CTL) kill T2 target cells incubated with WT-1/126 peptide. This demonstrates that the peptide is capable of eliciting a CTL response. As noted in Exhibit B, page 10, cytotoxic T-cells (CTL) incubated with WT-1/126 peptide kill target cells endogenously expressing WT-1. This demonstrates that the peptide is capable of eliciting a CTL response against cells expressing the WT-1 protein. As noted in Exhibit B, pages 11-12, cytotoxic T-cells (CTL) incubated with WT-1/126 kill CD34+ chronic myelogenous leukemia (CML) cells. The specification at least at page 8, lines 26-27, disclose that leukemias over-

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express WT-1. This demonstrates that the peptide is capable of eliciting a CTL response against tumor cells expressing HLA-A0201 and over-expressing WT-1.

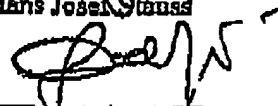
6. In summary, as demonstrated by this data, we conceived and reduced to practice the peptide containing the amino acid sequence RMFPNAPYL as defined by claims 1, 5, 7, 15, and 19 of the above-identified patent application prior to September 30, 1998.

7. I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further, that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 7-3-06

Date: 7-3-06

  
Hans Josef Stauss

  
Liqun Gao

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**Peptides ordered**

**HLA0201 motifs:**

huWT 10-18: ALLPAVPSL  
huWT 17-26: SLGGGGGCAL  
huWT 126-34: RMFPNAPYL  
huWT 187-95: SLGBQQYSV  
huWT 225-33: NLYQMTSQL  
huWT 235-43: CMTWNQMNL  
huWT 280-88: ILCGAQYRI  
huWT 441-49: NMTKLQLAL

huK103-12: ALSGVGGIRL  
huK116-24: KLKCDICGI  
huK231-39: GLPGTLYPV  
huK231-40: GLPGTLYPVI  
huK321-30: YLGAESLRPL  
huK373-81: LLLLSKAKL  
huK374-82: LLLSKAKLV  
huK410-18: GLIYLTNHI  
huK471-79: FLDHVMTYI

**K<sup>b</sup> motifs:**

muWT 45-52: GASAYGSL  
muWT 145-52: RNQGYSTV  
muWT 290-97: THGVFRGI  
muWT 330-37: CNKRYFKL

muG74-81: VFQVYPLI  
muG227-34: ACGLYHKM  
muG281-88: ACGLYFKL  
muG330-37: PAGGFMVV  
muG357-64: TAHLYQGL

**D<sup>b</sup> motifs:**

muWT 221-29: YSSDNL YQM  
muWT 126-34: RMFPNAPYL  
muWT 235-43: CMTWNQMNL  
muWT 437-45: MHQRNMTKL

muG234-42: MINGONRPLI  
muG125-33: EGKSNNTFL  
muG222-30: HYL CNACGL  
muG276-84: DPVCNACGL

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